

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

DELAWARE HEALTH
CORPORATION,

Plaintiff,

v.

MICHAEL O. LEAVITT,

Defendant.

CIV. NO. 07-829-SLR

* * * * *

**OPENING BRIEF OF PLAINTIFF DELAWARE HEALTH
CORPORATION IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT**

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NATURE AND STAGE OF THE PROCEEDINGS

Plaintiff Delaware Health Corporation, t/a Harbor Healthcare & Rehabilitation Center (“Harbor”) is a Medicare provider of skilled nursing facility services, located in the State of Delaware. Empire Medicare Services (“Empire” or the “Intermediary”) is Harbor’s Medicare Fiscal Intermediary, and accordingly is the agent of the United States Department of Health & Human Services (“DHHS”) that determines provider’s reimbursable costs. The Intermediary reviews reported reimbursable costs from nursing facilities (the “Cost Reports”), and makes adjustments/deductions as it determines appropriate in accordance with Medicare laws and policies.

Harbor reported its Medicare costs for fiscal years 1996 and 1997, and Empire reviewed and finalized Harbor’s costs for those years. More than four years after Harbor’s Medicare cost settlements were finalized for those fiscal years, Empire sent Harbor Revised Notices of Final Settlement for both fiscal years (Exhibits P-1, R-176 and P-2, R-185).¹ In those revised determinations, the Intermediary sought the return of identified Medicare program expenditures relating to the cost of therapy services provided to Harbor’s residents by a Harbor contractor.

Harbor appealed the revised determinations contained in Exhibits P-1 and P-2 (the “Revised Cost Settlements”). That appeal was heard by Medicare’s Provider Reimbursement Review Board (“PRRB” or “the Board”). After holding an evidentiary hearing, the Board ruled, three members to two, against Harbor on the limitations issue addressed in Section II of the Argument, *infra* pp. 8-11, and ruled unanimously in Harbor’s favor on the substantive issue addressed in Section III of the Argument, *infra* pp. 11-18, resulting in a reversal of the Intermediary’s revised determinations.

¹ The certified record of the administrative proceedings below have been filed by DHHS (Docket Item (“D.I.”) 13) and labeled pages 1-358. Referencing herein will be to the Exhibit and the page of the record (i.e., P-1, R-2).

The Administrator of the DHHS Centers for Medicare and Medicaid Services (“CMS”), the agency responsible for the administration of the Medicare program, acting on behalf of the Secretary of DHHS, reversed the findings of the PRRB with respect to the substantive issue, thereby reinstituting the Intermediary’s Revised Cost Settlements, and Harbor filed the instant appeal.

SUMMARY OF ARGUMENT

1. The Medicare Program reopened Harbor's finalized cost settlements for two fiscal years because of a concern that Harbor's therapy services contractor, Whitehorse, had fraudulently documented services to an extent that it had not provided those services at Harbor. While Harbor paid Whitehorse for all documented therapy services, Medicare has sought to recoup its reimbursement to Harbor for a percentage of those payments.

2. While not having reviewed any records from Harbor, Medicare took back a percentage of paid therapy services from Harbor, based on a settlement between Medicare and Whitehorse. Harbor contends that (a) that reopening of its 1996 and 1997 cost reports violated Medicare rules on cost report reopening, and (b) that Medicare provided no substantive evidence justifying any specific take-back of paid costs. Harbor contends that the Medicare action violates Medicare's own audit rules, and also does not comport with professional standards for utilizing sampling methodologies to generalize conclusions to a larger universe.

STATEMENT OF FACTS

Harbor's Cost Reports for both fiscal years 1996 and 1997 were finalized by the Intermediary on September 28, 1999.² The Intermediary re-opened those Cost Reports and issued revisions through a letter dated October 23, 2003, more than four years later. Prior to the re-opening, the Intermediary sent two pieces of correspondence to Harbor: (1) a letter dated August 21, 2002 (Exhibit P-3, R-194) indicating that the Office of Inspector General had informed Empire that a reopening of the 1996 and 1997 cost reports would be necessary; and (2) a letter of March 18, 2003 (Exhibit P-4, R-195) informing Harbor that the Intermediary "reserves the right to reopen [the subject] cost report when [it has] completed [its] review" Revised Final Settlement Notices containing the proposed adjustments were issued on October 23, 2003.

In the reopened Cost Reports, the Intermediary made adjustments to previously settled fiscal years, on the alleged basis that some of the costs reflected on Harbor's cost reports for 1996 and 1997 represent amounts paid by Harbor to an independent contracting therapy agency (the "Therapy Contractor") that is alleged to have fabricated services or levels of service and billed Harbor for services or levels of service not actually rendered. To the extent that Harbor reimbursed the Therapy Contractor based upon what the CMS contends were improper invoices from that contractor, the Intermediary is now seeking to remove the Therapy Contractor related costs from Harbor's Medicare cost reimbursement. The costs being removed are costs actually incurred by Harbor in payment for therapy services rendered to its residents, but Empire has claimed that the therapy company did not render the services, even though they were documented in the residents' records and billed to Harbor by the therapy services company.

² The amounts disallowed were \$27,659 for 1996, and \$68,978 for 1997. The total amounts of Medicare funds received by Harbor were \$630,731 and \$916,969, respectively.

While the services of the Therapy Contractor in question have been documented in Harbor's resident records, the Intermediary has offered no evidence to demonstrate that its allegations of wrongdoing on the part of the Therapy Contractor in connection with the services provided to Harbor are true, or, if true, to what extent. The Intermediary has presented no evidence below pointing to inappropriate billings for any specific services representing costs reimbursed by Medicare to Harbor. The Intermediary reviewed not a single record of Harbor on this subject. Rather, the Intermediary offered only the explanation that it utilized the same percent of "inappropriate" therapy billings at Harbor as it found in a one-month sample at an unrelated facility served by the same Therapy Contractor. (Exhibit I-7, R-140). The methodology for determining the findings of the one-month sample at the other facility was never disclosed. Nor has any justification ever been presented to compare Harbor to the other facility. The sole basis for the Intermediary's argument was the unsubstantiated double-level hearsay allegation to the effect that an unnamed "witness[es]" believes that the therapy company did "the same thing" at other facilities. (Exhibits I-7, R-140 and I-11, R-157). No individual was named, no further explanation was provided, and no live testimony was provided at the hearing on this critical subject. Harbor was not told of the identity of the person to whom the alleged hearsay allegation was made (by another unnamed individual). Needless to say, it was not possible for the PRRB or any party below to make inquiry concerning what that person might have meant by "the same thing."

To be specific, the case presented below by the Intermediary, in its entirety, is as follows:

1. The Intermediary's Final Position Paper before the PRRB consisted, in substance, of two sentences, which explained that the disallowance was based upon "information received from the United States Department of Justice." (Without indicating what that information was).

2. The Intermediary's response to the Interrogatories filed by Harbor indicated that no additional substantive evidence was relied upon in arriving at its decision.
3. The Intermediary presented the testimony of no witnesses at the PRRB evidentiary hearing.
4. The Intermediary's exhibits 6-12 (filed the day prior to the PRRB hearing in flagrant violation of the PRRB's regulatory discovery requirements, and contrary to the Intermediary's response to Harbor's Interrogatories) indicated that:
 - a. The conclusions of a review of therapy services by the Therapy Contractor at another nursing facility were applied to the services at Harbor to determine the alleged overpayment amount. (Exhibit I-7, R-140).
 - b. Fraudulent billing by the Therapy Contractor allegedly occurred in "various nursing homes in Delaware, Pennsylvania and Maryland." (Exhibit I-11) (unnamed source).
 - c. "Witness interviews indicated that the same thing occurred in all four facilities during the entire time the company served those locations." (Exhibit I-7, R-140) (unnamed source).

In adopting Harbor's position, the PRRB unanimously held, in pertinent part, as follows:

"The Board majority finds that the August 21, 2002 letter was an adequate notice of reopening and that it was within the three-year limit for reopening." (PRRB Decision at p. 8, R-31).

". . . [T]he Board finds that the sampling method used by the Intermediary in this case did not meet the relevant audit standards and cannot be upheld." (PRRB Decision at p. 9, R-32).

". . . [T]he Intermediary presented no testimony with regard to the nature of the fraud, its scope, or what procedures were utilized to select the sample that formed the basis of the disallowance" (PRRB Decision at p. 9, R-32).

"The Board's concerns with the sampling method relied upon by the Intermediary is based on a number of factors. While the Board accepts that Whitehorse [the Therapy Contractor] inflated some of its therapy claims, there is no direct evidence of the extent of the problem at the Provider's [Harbor's] facility. The record indicates that the only sample taken was from another facility. Although the auditor wrote that witness interviews indicate that the same practice occurred at all four facilities, there is no evidence of this in the record in the form of witness testimony, affidavits or other documents. The validity of using data

from another facility is, in itself, questionable. In addition, the sample only encompasses dates from one month during the two year period. The Board finds that a sample that includes only one of four providers and only one month out of a possible 96 months of data is both too small to yield meaningful results and not representative of the total population. The record also provides very little information about how the audit analysis was actually conducted. The process for eliminating the amount of the "unearned therapy costs" billed by Whitehorse [the Therapy Contractor] was developed from altered logs at one facility for the month of January 1996. The Board finds no evidence in the record to support the sample as a competent and valid basis for determining that the costs claimed by the Provider were not proper." (PRRB Decision at pp. 10-11, R-33 and 34).

". . . [T]he Board . . . finds that the Intermediary failed to document and identify the rationale for the method it utilized to make its adjustments." (PRRB Decision at p. 11, R-34).

"The Board finds that the Intermediary's failure to use any of the Provider's records in the sample that was used to reduce the Provider's therapy costs or to justify the rationale for the application of the sample that actually was used in making the reduction was improper." (PRRB Decision at p. 12, R-35).

The CMS Administrator overturned the PPRB's findings on this issue, holding the sampling methodology to be "valid and reasonable under the circumstances of this case" (Administrator Decision, pp. 5 and 6, R-6 and 7), for the following stated reasons:

1. Since the circumstances involved fraud, "unique methods were necessary;"
2. Situations involving fraud "are not necessarily addressed by typical auditing procedures;" and
3. "Factual findings" in a criminal matter need not be readjudicated in this administrative case, and are therefore adopted.

Harbor submits that (1) the Notice to Reopen was, as a matter of law, untimely, and (2) the CMS reversal of the Board was arbitrary and capricious and devoid of factual or legal basis. It is patent that the law does not allow an Intermediary to unilaterally toll the limitations period because it has failed to complete its review. To sanction such an exception would in effect render the limitations period meaningless.

ARGUMENT

I. Standard of Review.

Pursuant to 5 U.S.C. § 706, the final agency decision is to be upheld unless it is arbitrary, capricious, an abuse of discretion, contrary to law, or unsupported by substantial evidence when the record is reviewed as a whole. In making this determination, a reviewing court will substantially defer to the Secretary's construction of any ambiguous language in the Medicare Act, if the Secretary's construction is "based upon a permissible construction of the statute." MacKenzie Medical Supply, Inc. v. Leavitt, 506 F.3d 341, 346 (4th Cir. 2007), quoting from Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837, 843 (1984). The Third Circuit, in another Medicare case, has stated that the arbitrary and capricious standard "asks whether 'the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.'" Robert Wood Johnson University Hospital v. Thompson, 297 F.3d 273, 280 (3rd Cir. 2002), quoting in part from Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983).

- II. The Intermediary did not provide timely notice to reopen the final settlement for FYs 1996 and 1997 within the time-frame set forth in the Medicare regulations and the Provider Reimbursement Manual, Part 1, § 2931.1, and therefore was barred by Medicare law and policy from reopening the two final settlements.

A "reopening" is an affirmative action taken by an intermediary, the Board, or the Department of Health & Human Services, to re-examine or question the correctness of an already "final" determination. Provider Reimbursement Manual ("PRM"), § 2931.³ An intermediary's determination of payment may be reopened by the intermediary within three years

³ Exhibits P-5 and P-6.

of the date of the notice of payment or final settlement being revised. PRM, §§ 2931.1A and 2931.1G. Within that three-year time frame, the intermediary will reopen if CMS notifies the intermediary in writing that “such determination or such decision is inconsistent with the applicable law, regulations, or general instructions issued by HCFA.” PRM, § 2931.1C. [“HCFA” is the former name for CMS]. Unless a regulatory exception applies, no reopening may be made after the expiration of the three-year period. 42 CFR § 405.1885(a).

When an intermediary’s otherwise “final” determination is “reopened,” notice of such reopening must be mailed to the provider by the intermediary, and the notice must contain a “complete explanation” of the basis for revisions, and offer the provider an opportunity to comment, object, or submit evidence in rebuttal. 42 CFR § 405.1887 and PRM, Part 1, § 2932A. This is the legal requirement for acceptable notices of reopening, as set forth by CMS and DHHS themselves, in their regulations and formal program guidelines. There are no applicable exceptions to these requirements.

In the instant case, the Revised Notices of Final Settlement were issued on October 23, 2003, almost four years after the original “notices” (final determinations) were issued. (September 28, 1999).⁴

Intermediary admitted in that letter of August 21, 2002 that the three-year reopening period in this case expired on September 28, 2002. The Intermediary’s letter of August 21, 2002 (Exhibit P-3, R-194) (copy attached for reference at Tab 1 hereto) was the only correspondence issued by the Intermediary in this case within the required time period, but it is not a “notice of reopening” because that letter plainly did not meet the regulatory and manual requirements for a

⁴ The Intermediary’s letter of March 18, 2003, may have arguably met the substantive CMS requirements for a “reopening notice,” in that it notified Harbor that its Cost Reports were in fact being reopened (“the cost report is being reopened”), identified the subject of the revisions to be made, and provided a 30-day period for comment, etc., from Harbor. The March 18, 2003 letter, however, was also issued outside of the regulatory maximum three-year period for reopening a finalized cost settlement.

“complete explanation” (or any other type of explanation) of the proposed revisions to the original settlement. Nor does it provide Harbor with the opportunity to comment, object or submit evidence in rebuttal. In fact, the letter itself admits that it is not a notice of reopening. “Based on this letter, EMS reserves the right to reopen these costs reports when we have completed our review of the details of the OIG review.” (Exhibit P-3) (emphasis added).

Nevertheless, three of the five PRRB members agreed with the Intermediary that the letter of August 21, 2002 met the applicable standards for a “notice of reopening,” finding that the letter (a) called itself a “notice of reopening,” (b) noted that a reopening appeared necessary, and (c) “provided a reasonably clear explanation of why the reopening is necessary” by stating that there was an indication that “the Provider reported inflated therapy costs.” (PRRB Decision, p. 8). This conclusion was, as a matter of law, in direct contravention of the applicable regulations and guidelines. These authorities do not authorize the Intermediary to unilaterally toll the limitations period by way of what is in fact a reservations of rights letter while the Intermediary conducts the investigation which the authorities mandate must be completed within the three-year period. The purpose of the limitations period itself is to protect the Provider from being forced to contest stale claims long after the evidence to resist such claims was easily available. The Intermediary did not give notice of reopening, only notice that it was investigating “the details of the OIG review” and had not yet obtained sufficient evidence to reopen. Indeed, rather than conduct the investigation within the requisite three years, the Intermediary did not complete its investigation and reach any conclusions regarding reopening until more than a year after its August 21, 2002 reservation or rights letter with the issuance of the Revised Notice of Final Settlement on October 23, 2002. Notice that they are investigating a

matter is not, as a matter of law, a “complete explanation of the basis for the revisions.” The point is the Intermediary could not reopen because it had admittedly not completed its review.

Simply put, the Intermediary did not provide the required notice to reopen the instant cost settlements within the allowable three-year period.

The only exception to the three-year reopening limitation may occur when “it is found that such determination or decision was procured by fraud or similar fault by any party to the determination or decision.” 42 CFR § 405.1885(d), and PRM, § 2931.1F. In the instant case, there are only two parties to a determination or decision concerning Harbor’s cost reporting: Empire/CMS, and Harbor. There is no allegation in this case that the original cost settlements in question were procured in any respect by fraud or similar fault on the Harbor or Empire.

Accordingly, there exists no authority in this case for the Intermediary to reopen beyond the three-year general limitation established by federal regulation and policy. As a matter of law, the Board has no lawful authority to rewrite of the regulations and manual by creating a new exception to the three-year period; viz. a unilateral tolling by the Intermediary while the Intermediary performs a review.

III. CMS erred, as its upholding of the PRRB was arbitrary, capricious, and unsupported by substantial evidence.

In the instant case, a revision of final settlements was not based upon a determination that any particular cost reported by Harbor was inappropriate. Nor was it even based upon a review of any particular record of Harbor. The Intermediary accepted the anonymous statement allegedly made in the criminal investigation of another nursing facility having no relationship whatsoever with Harbor (Exhibit I-7, R-140), that the same thing occurred at all four facilities during the entire time the company served those locations. Building on the acceptance of that statement(s), the Intermediary determined that the percentage of the therapy costs estimated to be

bad was developed from altered records at one location for the month of January 1996. “The percentage bad from one month at ... one facility [not Harbor] was then applied to all occupational therapy speech and invoices to all four facilities [including Harbor].” The Intermediary concluded, without reviewing the Therapy Contractor’s billing to Harbor or any records of Harbor, that a one month review result at an unrelated facility was to apply to two years of therapy services rendered at Harbor.

While a sampling methodology may be the basis under applicable standards for an appropriate Intermediary determination, it is only appropriate when proper standards are followed in identifying a “universe,” and culling a sample. (Testimony of Jennifer Schumi, Ph.D., at 106-112, 121, R-95, 96 and 99). An examination of applicable standards indicates that the methodology utilized by the Intermediary in this case falls far short of the mark, and cannot be upheld.

The federal government’s Medicare Intermediary Manual, Part 4, §§ 4112, et seq. (Exhibit P-7, R-206), provides “Standards for Audit Under Medicare.” This manual provision recognizes the authority of the Government Accounting Standards (GAS) issued by the Comptroller General of the United States, as applicable to all audits performed by or for any Federal agency. Per the manual, an auditor must meet the following standard:

Ensure that evidence obtained during the course of the audit is sufficient to enable the auditor to support conclusions, adjustments, and recommendations. Make sure that there is enough factual and convincing evidence so that a prudent person can arrive at the same conclusion of fact as the auditor. In additional, evidence must be competent and relevant. That is, evidence must be valid and reliable and have a logical relationship to the issue/subject under review.

Id., at § 4112.4(B) (Exhibit P-7, R-222).

The manual describes four types of evidence that may be used: physical evidence, documentary evidence, analytical evidence, and testimonial evidence. The last category is

described as the least reliable form of evidence that should be corroborated with other forms of evidence. Id. The manual describes sampling as the application of audit procedures to less than 100 percent of the items within a class - to evaluate some characteristics of the balance of the class. Id. While a sampling approach may be “nonstatistical,” the findings “must be scientifically established to support adjustments.” Id. Ultimately, the auditor must document that the evidence obtained and procedures applied provide “sufficient competent evidence” to support the audit conclusions. Id. The auditor should test the various types of evidence considered, and retain documentation, and where materiality is a factor, the audit should define materiality within the scope and objective of the audit. Id.

The applicable GAO standards also address audit procedures. GAO-03-673G

Government Auditing Standards, Chapter 7 (Exhibit P-8). The following standards must be met:

- 7.52 Evidence should be sufficient, competent, and relevant to support a sound basis for audit findings, conclusions and recommendations:
- a. Evidence should be sufficient to support the auditors’ findings. In determining the sufficiency of evidence, auditors should ensure that enough evidence exists to persuade a knowledgeable person of the validity of the findings. When appropriate, statistical methods may be used to establish sufficiency.
 - b. Evidence is competent if it is valid, reliable, and consistent with fact. In assessing the competence of evidence, auditors should consider such factors as whether the evidence is accurate, authoritative, timely, and authentic. When appropriate, auditors may use statistical methods to derive competent evidence.
 - c. Evidence is relevant if it has a logical relationship with, and importance to, the issue being addressed.

Id., at § 7.52.

The GAO standards provide that, where auditors are unable to obtain sufficient, competent, and relevant evidence about the validity and reliability of their data, they should consider:

- a. seeking evidence from other sources;
- b. redefining their audit objectives to eliminate the need to use the data; or
- c. using the data, but clearly indicating the data's limitations, and refraining from making unwarranted conclusions. Id., at § 7.61.

Accordingly, applicable audit standards allow the intermediary to utilize sampling methodologies to determine overpayments. Nevertheless, standards are set that require the use of competent evidence sufficient to support the adjustments. The evidence must be reliable and have a logical relationship to the issue/subject under review. The materiality of evidence used must be defined. The facile extrapolation of the percentage of one month's billing at another nursing facility, without ever even glancing at Harbor's records, is fatally flawed methodology. In the instant case, the "universe" was all rehabilitation costs of Harbor for the 96 months in question. The "sample," however, was not taken from any rehabilitation costs reported by Harbor, nor was it taken from any costs of any type reported by Harbor. No costs reported by Harbor were included in the "sample," and no justification for the creation and use of the sample was provided by the Intermediary. The question presented, then, is can such a sampling be considered competent and valid "evidence" of alleged overpayments to Harbor?

This is not a matter of first impression - the PRRB has not hesitated to reverse an Intermediary survey where the sampling methodology was not supported by the record. For example, the Board found that there was no documentation to indicate how the Intermediary selected the sample in Providence Medical Center v. BCBS Association, PRRB Hearing Dec. No. 99-D20 (1/22/99), reported at CCH, Medicare and Medicaid Guide, ¶ 80, 157. (Exhibit P-9,

R-231). Reviewing federal courts have also agreed that, once demonstrated, sampling methodology used in Medicare reimbursement may be given a fairly wide latitude, but the audit methods used must be “valid and reliable.” Webb v. Shalala, 49 F.Supp.2d 1114 (D. Ark. 1999), reported at CCH, Medicare and Medicaid Guide, ¶ 300, 330. (Exhibit P-10, R-241).

Several criteria have been identified as being necessary for the sampling methodology to be “valid and reliable.” Where the data used to develop the sample were not the best available data (e.g., out-of-date), with no appropriate justification, the sampling methodology is unacceptable. County of Los Angeles v. Shalala, 192 F.3d 1005 (D.C. Cir. 1999), reported at CCH, Medicare and Medicaid Guide, ¶ 300, 334. (Exhibit P-12, R-257). An Intermediary’s sampling methodology was rejected by the PRRB where the universe utilized to develop the sample contained data not relevant to the provider. Hospital San Francisco, Inc. v. Cooperative de Seguros de Vida de Puerto Rico, PRRB Hearing Dec. No. 2003-D57 (9/12/03), reported at CCH, Medicare and Medicaid Guide, ¶ 81, 043, Rev’d, CMS Administrator, reported at CCH, Medicare and Medicaid Guide, ¶ 81, 089. (Exhibit P-13, R-271).

Ultimately, the sample utilized by the Intermediary in the instant case fails the most critical test. It does not meet the definition of “sampling” contained in the Medicare Intermediary Manual (§ 4112.4(B)). As Dr. Schumi, an expert statistician, testified, there are standards for creating appropriate samples, both stated explicitly in the Medicare Intermediary Manual, and such as are generally utilized by professional statisticians. (Testimony of Jennifer Schumi, Ph.D., at 106-112, R-95-96). One is unable to determine whether the actions of the Intermediary in this case might have met those standards, as the necessary documentation of underlying factual analysis and methodology have not been presented by the Intermediary in this case for review. (Testimony of Jennifer Schumi, Ph.D. at 106-112, 125-126, R-95-96 and 100).

Such a failure, in itself, violates the Medicare Intermediary Manual requirements for the use of a sample.

The PRRB found that the “sampling methodology” utilized by the Intermediary did not meet Medicare standards in that there was no documentation of evidence or procedures, and no evidence that was competent, relevant and logically related to the same issue under review. (PPRB Decision, p. 9, R-32). The Board further found that the data used cannot be said to be representative of the population in question, and that there was no evidence in the record to support the sample used (i.e. one month at another facility) as being competent and a valid basis for the disallowances issued, (i.e. 96 months at Harbor) (i.e. extrapolating the percentage). (*Id.*, at 11, R-34).

Despite the PRRB’s finding that there was no evidence in the record to support the Intermediary’s disallowance in this case, the CMS Administrator overturned the PPRB’s findings on this issue, holding the sampling methodology to be “valid and reasonable under the circumstances of this case” (Administrator Decision, pp. 5 and 6, R-6 and 7), for the following stated reasons:

1. Since the circumstances involved fraud, “unique methods were necessary;”
2. Situations involving fraud “are not necessarily addressed by typical auditing procedures;” and
3. “Factual findings” in a criminal matter need not be readjudicated in this administrative case, and are therefore adopted.

The ruling fails to discuss why the situation was an “atypical” and “unique” circumstance or why such circumstances allow for the use of a method that departs from the mandate that it not be arbitrary and capricious based on evidence that is sufficient, competent and relevant, and the method employed be based on scientific data.

Nor did the Administrator identify what “factual findings in the criminal matter did not have to be readjudicated.” The criminal matter against the Therapy Contractor involved a two-count indictment in the case of U.S. v. Pappert and Waxler, in the U.S. District Court for the District of Delaware (Exhibit I-11, R-157). Both defendants pleaded guilty to count one which alleged a conspiracy that inflated invoices were “generally sent... to the nursing homes to which [the Therapy Contractor] had provided therapy services, and that the overt act of “sending such invoices in January, 1996, to the offices in Pennsylvania of the nursing home to which it had provided services.” (Count One). The record below was barren of any evidence concerning the nature and extent of any alleged wrong doing in connection with therapy services rendered to Harbor. The Administrator did not and could not find any basis to apply collateral estoppel to the guilty plea on any issue that would support the methodology employed by the Intermediary in the within case.

The Administrator cited no provisions of statute, regulation, or program manual to justify or explain the above conclusions. No attempt was made to identify the applicable legal guidelines in a case such as this, nor was an attempt made to explain why applicable law and guidelines do not themselves indicate that they do not apply in “a case such as this,” however that might be defined. No attempt was made to identify the “factual findings” that were adopted from the criminal matter, and the evidentiary documents from the criminal matter do not themselves provide any such explanation. In sum, no facts or legal rationale were provided by the Administrator for overturning the PRRB’s ruling on this issue.

It is to be noted that the Administrator, in Footnote 11 (R-7) of his Decision, stated that Harbor had the opportunity to “rebut” the Intermediary’s “findings,” and did not do so. First, as the PRRB pointed out, the only information presented to Harbor by the Intermediary was filed

with the PRRB the day before the evidentiary hearing (years after the Revised Settlements were issued, and years after the Intermediary's response to Harbor's Interrogatories indicated the availability of no evidence on the part of the Intermediary). Second, and more importantly, the "offer" to present rebuttal evidence was a red herring. Harbor met all regulatory requirements through the therapy services provider's records indicating that the services were provided to Harbor's residents. The Intermediary questioned the veracity of those records without reviewing them, and then gave Harbor the "opportunity" to prove that they had not been falsified by the therapy contractor. The Intermediary has always known that it is impossible for Harbor to affirmatively "prove" that some or all of the records created by the therapy provider were not false. If the Intermediary wished to seek the return of payments made for therapy services, it held the burden to demonstrate the inaccuracy of Harbor's records. It has made no attempt to do so.

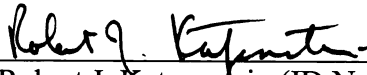
In its most favorable light, the agency's "evidence" must be subjected to tests of adequacy for "sampling" methodology, and it has been shown that the "evidence" presented on behalf of the agency fails to meet any acceptable test, whether that of the Medicare program audit guidelines, or that of professional standards utilized by statisticians. The agency decision was accordingly not supported by substantial evidence. In sum, the agency's decision was arbitrary and capricious, and unsupported by substantial evidence.

CONCLUSION

Based on the foregoing points and authorities, Harbor respectfully submits that the Court should reverse the Administrator's decision to uphold the revised determinations contained in the Revised Final Settlement Notices for 1996 and 1997.

Respectfully submitted by:

SMITH, KATZENSTEIN & FURLOW LLP



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Dated: June 13, 2008

TAB 1

11/05/2003 WED 16:10 FAX



MEDICARE
Part A Intermediary
Telephone: 1-877-567-7205

George E. Porette- Manager- A&R Dept.- Telephone (914) 248-3202 Facsimile (914) 248-3737

Mr. Ronald Shafer
Administrator
Harbor Healthcare & Rehab Center
301 Oceanview Blvd.
Lewes, Delaware 19958

August 21, 2002

Re: Reopening of the 1996 and 1997 cost reports
for Medicare purposes
Provider: Harbor Healthcare & Rehab Center
Provider No.: 08-5034

Dear Mr. Shafer:

The Office of Inspector General (OIG) has informed Empire Medicare Services (EMS)- Audit & Reimbursement Department that a reopening of the 1996 and 1997 cost reports are necessary. Our review of the correspondence we have received indicates that the Provider reported inflated therapy costs for those cost reports years.

A review of the Notice of Program Reimbursement (NPR) for the both cost report years indicate that they were final settled on 9/28/99. Since the three year window for the 12/31/96 and 12/31/97 cost reports does not expire until 9/28/02, it is still within the three year reopening limit as set forth in HCFA Pub. 15-1 section 2931.1. Based on this letter, EMS reserves our right to reopen these cost reports when we have completed our review of the details of the OIG review. At this writing, we are unsure whether additional information will be necessary from the provider.

EMS will propose the supplemental adjustments to each of the cost report years and send you a copy of those adjustments. Upon your acceptance of those adjustments or 14 days after they are sent, whichever is earlier, we will forward those supplemental adjustments to our Syracuse office to begin processing the reopenings. A revised NPR can be expected 120 days after I notify Syracuse that the supplemental adjustments have been finalized.

If you have any questions, you can contact me at (914) 248-3202.

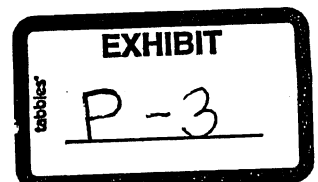
Sincerely,

George E. Porette
Manager- Audit & Reimbursement Dept.

*per Stephanie -
Has not seen this
anywhere else*

Cc: Dave McGrath- EMS
Angie Tyson- EMS
Ed Stern- EMS
Ed McCusker- OIG

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 13th day of June, 2008, a copy of the Opening Brief of Plaintiff Delaware Health Corporation in Support of its Motion for Summary Judgment was served in the manner indicated on the following:

BY E-FILE

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